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BIOMET®
MANUFACTURING CORP.

MAR 20 2008

## 510(k) Summary

**Preparation Date:** 23 January, 2008

**Applicant/Sponsor:** Biomet Manufacturing Corporation

**Contact Person:** Gary Baker, MS RAC

**Proprietary Name:** Vanguard™ Knee System Titanium Femoral Components

**Common Name:** Titanium femoral knee components

**Classification Name:** Knee joint, patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR § 888.3560)

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**
Biomet Titanium Femoral Component – K981996 (Biomet Inc.)
Maxim® Accel Knee System – K023546 (Biomet Inc.)
Vanguard™ SSK Knee System – K042757 (Biomet Inc.)

**Device Description:** The Vanguard™ Knee System Titanium Femoral Components have the same design as the predicate Vanguard™ femoral knee components originally cleared as the Maxim® Accel Knee System femoral components. The difference in material offers the opportunity for total knee replacement to those patients with metal sensitivity to the nickel element of the predicate Co-Cr-Mo Cobalt – Chromium alloy femoral knee components.

**Indications for Use:**
1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved.
2. Failure of previous joint replacement procedure.
3. Correction of varus/valgus or post-traumatic deformity.
4. Correction or revision of unsuccessful osteotomy, or arthrodesis.

- Device designed for use in patients with metal sensitivity.
- Standard surgical and rehabilitative procedures are indicated with this device.
- The device is a single-use device intended for use with bone cement.

**Summary of Technologies:** The Vanguard™ Knee System Titanium Femoral Components have the same indications for use and the same design technology as the predicate devices.

**Mailing Address:**
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
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**Shipping Address:**
56 East Bell Drive
Warsaw, IN 46582

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**Non-Clinical Testing:** Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

**Clinical Testing:** None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet, Inc.
% Mr. Gary Baker
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581

MAR 20 2008

Re: K080204
Trade/Device Name: Vanguard™ Knee System Titanium Femoral Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prothesis
Regulatory Class: II
Product Code: JWH
Dated: January 23, 2008
Received: January 28, 2008

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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## SECTION 4 - INDICATIONS FOR USE

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Device Name: Vanguard™ Knee System Titanium Femoral Components

Indications for Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved.
2. Failure of previous joint replacement procedure.
3. Correction of varus/valgus or post-traumatic deformity.
4. Correction or revision of unsuccessful osteotomy, or arthrodesis.

- Device designed for use in patients with metal sensitivity.
- Standard surgical and rehabilitative procedures are indicated with this device.
- The device is a single-use device intended for use with bone cement.

Prescription Use ___YES___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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